JAN 15 2010

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ABAXIS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K091052

1. Applicant Information:

Date Prepared:	January 12, 2010
Name:	Abaxis, Inc.
Address:	3240 Whipple Road Union City, CA 94587
Contact Person:	Dennis M. Bleile, PhD
Phone Number:	(510) 675-6515
Fax Number:	(510) 405-8871

2. Device Information:

Classification	Class II
Trade Name:	Piccolo® C-Reactive Protein Test System
Classification Name:	C-Reactive Protein Test system 866.5270

3. Identification of legally marketed device to which the submitter claims equivalence:

The following table identifies the legally marketed device to which Abaxis claims equivalence:

Predicate Device			
Predicate Device	**Manufacturer**	**510(k) Number**	**Date of SE Determination**
High Sensitivity C-Reactive Protein Synchron LX20	Beckman Coulter, Inc. (Brea, CA)	K070626	05/04/07

4. Description of the Device:

The Piccolo MetLyte Plus CRP Reagent Disc (which contains the Piccolo C-Reactive Protein Test System) is designed for lithium heparinized whole blood, lithium heparinized plasma, and serum, only. The disc meters the required quantity of sample and diluent, mixes the sample with diluent, and delivers the mixture to the

Summary of Safety and Effectiveness (*continued*)

reaction cuvettes along the disc perimeter. The diluted sample mixes with the reagent beads, initiating the chemical reactions that are then monitored by the analyzer.

5. Statement of Intended Use:

The Piccolo C-Reactive Protein Test System used with the Piccolo xpress Chemistry Analyzer is intended to be used for the in vitro quantitative determination of CRP concentration in lithium heparinized whole blood, lithium heparinized plasma, or serum in a clinical laboratory setting or point of care location. This test is not intended for high sensitivity CRP measurement.

6. Summary of the technological characteristics of the new device in comparison to those of the predicate device:

Table 1 outlines the technological characteristics of the Piccolo C-Reactive Protein Test System in comparison to the legally marketed predicate device.

Summary of Safety and Effectiveness (continued)

Table 1:
Specification Comparison: Piccolo C-Reactive Protein Test System & Predicate Device

	Piccolo xpress Chemistry Analyzer	Beckman Synchron LX20 Chemistry System K070626
Intended Use	Quantitative analysis of C-Reactive Protein	Quantitative analysis of C-Reactive Protein
Methodology	Enhanced latex-agglutination turbidimetric immunoassay	Particle-agglutination rate turbidimetric immunoassay
Sample Type	Lithium heparinized whole blood, lithium heparinized plasma, and serum	Plasma and serum
Dynamic Range, Lower Limit	5 mg/L	0.2 mg/L
Reagents	Dry test-specific reagent beads and liquid diluent; reconstitution performed by analyzer Active ingredients: Anti-CRP antibody-coated latex particles (latex particle-bound mouse monoclonal anti-CRP antibody) Anti-CRP goat antibody	Liquid reagents Active ingredients: Anti-CRP antibody-coated particles (particle-bound goat and mouse anti-CRP antibody)
Temperature of Reaction	37°C	37°C
Calibration	Bar code with factory calibrated lot specific data	Single-point adjusted, pre-determined calibration curve
Assay Range	5.0 – 200.0 mg/L	0.2 – 80.0 mg/L (60 – 380.0 mg/L ORDAC*)
Testing Environment	Professional use	Professional use
Sample Size	Approximately 100 µL	20 µL (12 µL ORDAC*)

* Beckman LX20 has an "Overrange Detection and Correction" for samples that exceed the 80.0 mg/L limit. This is an automated process within the analyzer that retests with a smaller sample volume.

Note: The Beckman system has been cleared for "high sensitivity" measurements, while the Abaxis system is seeking clearance for a "conventional, quantitative CRP" method, only. Still, The Beckman and the Abaxis systems share sufficient test system and performance characteristics so that the Synchron LX20 CRP assay may serve as the legal and functional predicate.

Summary of Safety and Effectiveness (continued)

7. Brief discussion of the clinical and nonclinical tests relied on for a determination of substantial equivalence.

Tables 2 & 3 summarize the results of clinical and non-clinical tests performed using the Piccolo C-Reactive Protein Test System.

Linearity:

Table 2:
Summary of Linearity

	C-Reactive Protein
Slope	1.037
Intercept	-0.764
Corr. Coefficient	0.997

Precision:

Precision studies were designed to evaluate within-run and total precision of the C-Reactive Protein Test System when run on the Piccolo xpress Chemistry Analyzer.

Table 3:
Within-Run and Total Precision for C-Reactive Protein, Assayed on the Piccolo xpress Chemistry Analyzer

Analyte	Within-Run	Total
	C-Reactive Protein (mg/L)	
Serum Level 1 (n = 80)		
Mean	8.3	8.3
SD	0.70	0.81
%CV	8.4	9.8
Serum Level 2 (n = 40)		
Mean	8.1	8.1
SD	0.49	0.51
%CV	6.1	6.3
Serum Level 3 (n = 40)		
Mean	8.8	8.8
SD	0.54	0.54
%CV	6.2	6.2

Summary of Safety and Effectiveness (continued)

Table 3 (continued)

Analyte	Within-Run	Total
	C-Reactive Protein (mg/L)	
Plasma 1 (n = 40)		
Mean	34.5	34.5
SD	1.04	1.09
%CV	3.0	3.2
Plasma 2 (n = 40)		
Mean	105.5	105.5
SD	2.06	2.30
%CV	1.9	2.2
Control Level 1 (n = 80)		
Mean	33.0	33.0
SD	1.21	2.12
%CV	3.7	6.4
Control Level 2 (n = 80)		
Mean	108.0	108.0
SD	1.88	3.14
%CV	1.7	2.9

Sample Type Comparison:

A study was conducted to examine and compare results for lithium heparinized whole blood, lithium heparinized plasma, and serum on the Piccolo® xpress Chemistry Analyzer.

Lithium heparinized whole blood, lithium heparinized plasma, and serum comparability was established for CRP.

8. Conclusions

The clinical and non-clinical tests performed for CRP, when run on the Piccolo xpress Chemistry Analyzer, demonstrate that the test system is as safe, effective and performs as well as the legally marketed device identified above.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center-WO66-G609
Silver Spring, MD 20993-0002

JAN 15 2010

Abaxis, Inc
c/o Dennis M. Bleile
Director of Assay Performance & Compliance
3240 Whipple Rd
Union City, California 94587

Re: k091052
Trade/Device Name: Piccolo® C-reactive Protein (CRP) Test System
Regulation Number: 21 CFR §866.5270
Regulation Name: C-reactive protein immunological test system
Regulatory Class: II
Product Code: DCN
Dated: January 5, 2010
Received: January 7, 2010

Dear Mr. Bleile:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Steven Philip

For Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____ K091052_____

Device Name: **Piccolo® C-Reactive Protein Test System**

Intended Use:

The Piccolo® C-Reactive Protein Test System used with the Piccolo xpress™ Chemistry Analyzer is intended to be used for the in vitro quantitative determination of CRP concentration in lithium heparinized whole blood, lithium heparinized plasma, or serum in a clinical laboratory setting or point of care location. This test is not intended for high sensitivity CRP measurement.

Indications for Use:

C-Reactive Protein test results aid in the evaluation of infection, tissue injury, and inflammatory disorders in conjunction with other laboratory and clinical findings.

Prescription Use ___X___ (Per 21 CFR 801.109) OR Over- The Counter Use _____ (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) k091052